



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 28 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Paul Dias
ZOLL Medical Corporation
32 Second Avenue
Burlington, MA 01803-4420

Re: K010257
ZOLL M Series
Regulatory Class: III (three)
Product Code: 74 MKJ
Dated: January 26, 2001
Received: January 29, 2001

Dear Mr. Dias:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

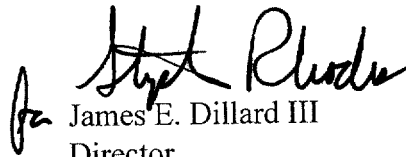
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further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III". To the left of the signature is a small, stylized mark that looks like a lowercase "j" or "f".

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Page 1 of 2

510(k) Number (if known): K010257

Device Name: ZOLL M Series

Defibrillator Function

Indications for Use – Manual Operation

Use of the ZOLL M SERIES in the manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

The ZOLL M SERIES contains a standard DC defibrillator capable of delivering up to 360 joules of energy. In manual mode, it may also be used for synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference.

This product is to be used only by qualified medical personnel for the purposes of converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

Indications for Use – Advisory Function

The advisory function should only be used to confirm ventricular fibrillation and ventricular tachycardia (greater than 150 beats per minute) in patients meeting the following clinical criteria:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Division of Cardiovascular & Respiratory Devices
510(k) Number K010257

Prescription Use X
(Per 21 CFR 801.109)

or

Over-The-Counter-Use _____
(Optional Format 1-2-96)

INDICATIONS FOR USE

Indications For Use

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Indications for Use – Semiautomatic Operation (if equipped)

The ZOLL M SERIES is designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the operator of the device controls the delivery of the shock to the patient. It is specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated in a medically-approved patient care protocol.

The ZOLL M SERIES must be prescribed for use by a physician or medical advisor of an emergency response team.

Use of the ZOLL M SERIES in the semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

Pacemaker Function (if equipped)

Indications for Use — Pacemaker

This product may be used for cardiac pacing in conscious or unconscious patients for up to a few hours duration as an alternative to endocardial stimulation. The purposes of pacing include:

1 Resuscitation from standstill or bradycardia of any etiology:

Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug induced standstill (due to procainamide, quinidine, digitalis, β -blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes-Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

2 As a standby when standstill or bradycardia might be expected:

Noninvasive pacing may be useful as a standby when cardiac arrest or symptomatic bradycardia might be expected due to acute myocardial infarction, drug toxicity, anesthesia or surgery. It is also useful as a temporary treatment in patients awaiting pacemaker implants or the introduction of transvenous therapy. In standby pacing applications, noninvasive pacing may provide an alternative to transvenous therapy which avoids the risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis and mechanical or electrical stimulation of ventricular tachycardia or fibrillation associated with endocardial pacing.

3 Suppression of tachycardia:

An increase in heart rate from external pacing often suppresses ventricular ectopic activity and may prevent tachycardia.